

Attorney Docket No. 9310.28CT
In re: Goudsmit et al.
Serial No.: 09/760,085
Filed: January 12, 2001

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REMARKS

Claims 16-21, 28-31, 39-41, 43 and 45-58 are pending in this application. Claims 45-58 are canceled herein without prejudice. In light of these claim cancellations and the following remarks, applicants respectfully request reconsideration of the pending application and entry of the present amendment in order to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

I. Rejection under 35 U.S.C. § 102(b)

The Office Action states that claims 16-21, 28-31, 39-41 and 43 are rejected as allegedly anticipated by Bastian et al. Specifically, although these claims were acknowledged by the Examiner and her supervisor to be allowable pursuant to a telephone interview on October 5, 2004, in which Examiner Tung, Examiner Horlick and Supervisory Examiner Benzion participated, they are now rejected on the basis that the term "consisting essentially of" is being construed as equivalent to "comprising" and are thus allegedly anticipated by Bastian et al. Specifically, the Examiner states that if it is applicants' contention that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicants have "...the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicants' invention." (citing *In re De Lajarte*, 337 F3d 870; 143 USPQ 256 (CCPA 1964) and *Ex parte Hoffman* 12 USPQ2d 1061 (Bd. Pat. App. & Inter. 1989).

Use of the phrase "consisting essentially of" in the claims

As discussed during the October 5, 2004 telephone interview, applicants direct the Examiners' attention to MPEP § 2111.03, wherein the phrase "consisting essentially of" is described as meaning that the scope of the claim is limited to the specified materials and "those that do not materially affect the basic and novel characteristics of the claimed invention." (citing *In re Hertz*). The term "consisting essentially of" occupies a middle ground between "consisting of" and "comprising." The Office Action disregards this distinction to state that "consisting essentially of" is the same as "comprising." However

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it is clear that the "consisting essentially of" language is intended to occupy the middle ground of limiting the scope of the claims to the specified materials and those that do not affect the basic and novel characteristics of the claimed invention.

Thus, in the context of the second liquid of the methods of this invention, this phrase is to be interpreted to mean that, in addition to the materials specifically recited in the claims, the liquid excludes alcohol groups but can include materials of this invention that do not affect the functional capabilities of the liquid to facilitate binding of nucleic acid to a solid phase. Such materials (e.g., Tris-HCl; Triton X-100; NaOH; H₂O) are described in the specification on page 7, lines 19-32.

In response to the Examiner's statement that the phrase "consisting essentially of" is being construed to mean "comprising" and that the applicants must show that the introduction of additional components would materially change the characteristics of the claimed invention, applicants direct the Examiners' attention to the Bastian et al. reference cited in this rejection. In particular, as applicants have pointed out in past responses, the invention set forth in the Bastian et al. patent and corresponding PCT publication is based on the proposal by Bastian et al. that variations in the concentration of materials containing alcohol groups in a binding solution influenced the binding characteristics of single stranded nucleic acid or double stranded nucleic acid. Applicants refer the Examiner to column 4, lines 17-43, of the Bastian et al. patent, wherein it is stated:

FIG. 1 shows the binding of single-stranded/double-stranded nucleic acid exemplified by single-stranded RNA and double-stranded DNA. Described here is the RNA/DNA binding from a tissue lysate to a mineral support as a function of the concentration of a material containing alcohol groups (here, ethanol) and a chaotropic substance (here, GTC). Under the condition that the concentration of one of the substances, alcohol or chaotropic substance, is constant, it is found that at a high alcohol concentration and/or amount of chaotropic substance, both types of nucleic acid (RNA/DNA) are bound to the mineral support. If the concentration of one or both substances (alcohol or chaotropic substance) becomes less than a defined value, none of the nucleic acids will bind to the

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mineral support to any substantial extent. Surprisingly, in between, RNA and DNA will bind to the mineral support to such different extents as can be made use of for the separation of the nucleic acids. Thus, proceeding from cells, and after lysis of the cells with a high concentration of chaotropic substances, the concentrations of chaotropic substance and material containing alcohol groups can be adjusted by subsequent addition of a material containing alcohol groups or a mixture of material containing alcohol groups and water or buffer such that a selective binding of the RNA is achieved while the DNA remains in the breakthrough. In the example according to FIG. 1, concentrations of 1.75 M GTC and 30% by volume of ethanol would be selected in order to achieve a separation of RNA from DNA by fractional binding. (Emphasis added.)

Thus, the teachings of the Bastian et al. patent are clearly directed to methods of separating single stranded nucleic acid from double stranded nucleic acid by altering the concentration of alcohol. Notably, the presence of alcohol in reagents used for binding nucleic acids materially affects the basic characteristics of the methods of binding nucleic acid as proposed by Bastian et al. and therefore would affect the functional capability of the claimed liquid to facilitate binding of nucleic acid to a solid phase. Thus, the phrase "consisting essentially of" as used in the claims presented herein is technically distinct in its meaning that the second liquid employed in the methods of this invention has the basic and novel characteristics of consisting essentially of material selected from the group consisting of: a) a chaotropic agent; b) a chaotropic agent and a chelating agent; c) a chaotropic agent and divalent positive ions; and d) a chaotropic agent, a chelating agent and divalent positive ions, which operate in the claimed methods in isolation of reagents containing alcohol groups that would materially change the characteristics of the invention, according to the disclosure in Bastian et al.

Furthermore, applicants have demonstrated throughout the disclosure and in the Examples set forth in the instant specification that the basic and novel characteristic of the claimed invention is the successful separation of single and double stranded nucleic acid in the absence of materials containing alcohol groups. Thus, applicants have met the

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standard as set forth in *In re De Lajarte*, cited by the Examiner, of showing the basic and novel characteristics of the claimed invention and that the introduction of materials containing alcohol groups would materially change these characteristics. Thus, for at least these reasons, applicants submit that claims 16-21, 28-31, 39-41 and 43 are not anticipated by Bastian et al. and applicants respectfully request the withdrawal of this rejection.

In response to the Examiner's comments in the present Office Action that the present rejection has been maintained because allegedly there is no evidence in the applicants' response "...showing the characteristics of the instant method for separating single stranded nucleic acid from double stranded nucleic acid without or with using alcohol," applicants point out that such a showing is not what is set forth in the MPEP, but rather, according to MPEP § 2111.03 citing *In re De Lajarte*, the burden on the applicants, as the Examiner emphasized in the November 1, 2005 Office Action, is to show that the introduction of additional steps or components would materially change the characteristics of applicants' invention. Applicants met this burden in the response filed February 28, 2006 by demonstrating that the prior art actually provides such evidence, as stated above. Thus, applicants believe this rejection has been overcome and respectfully request its withdrawal.

III. Rejection under 35 U.S.C. § 112, first paragraph

The Office Action states that claims 45-58 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter.

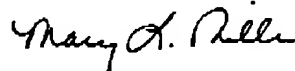
Claims 45-48 are canceled herein without prejudice, thereby mooting this rejection and applicants respectfully request its withdrawal.

For the foregoing reasons, applicants believe that all of the pending rejections have been adequately addressed and that the claims as presented are in condition for allowance. The Examiner is encouraged to contact the undersigned directly if such contact will expedite the examination and allowance of the pending claims.

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No fee is believed due with this response. However, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



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CERTIFICATE OF FACSIMILE TRANSMISSION

Date of Deposit: July 17, 2006

I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office to 571-273-8300 under 37 CFR 1.8 on the date indicated above and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Tracy Wallace